REMARKS

The Amendments

Support for new claim 32 is found in the specification at page 6, third full paragraph. The amendments do not narrow the broadest scope of the claims.

It is submitted that the above amendments would put the application in condition for allowance or materially reduce or simplify the issues for appeal. The amendments do not raise new issues or present new matter. The amendments have been made merely to add a further dependent claim recitation, which clearly falls within the scope of the already examined subject matter. Accordingly, it is submitted that the requested amendments should be entered.

The Rejection under 35 U.S.C. §112, first paragraph

The rejection of claims 1-3, 5-12, 14 and 17 under 35 U.S.C. §112, first paragraph, is respectfully traversed.

Applicants refer to their previous arguments and incorporate them herein by reference. The following points are made for further emphasis of those arguments.

Applicants reiterate that the novelty of their process invention – in its broadest sense – is that a controlled release drug formulation is locally administered by injection for the local elimination of normal but undesired tissue. This invention, in this scope, is clearly described by the disclosure. The exact language is even in the original claims (see MPEP §2163 (I)(A) stating: "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)."). The invention is applicable to any drugs for elimination of

normal but undesired tissue. Many such drugs are known in the art and numerous representative examples of such drugs are provided by the instant disclosure; see, e.g., page 4, second paragraph, of the disclosure. Further, the method is applicable to eliminating or reducing any normal but undesired tissue in a patient for which the selected drug is capable of eliminating or reducing. Again, many examples are known in the art of drugs for eliminating or reducing selected tissue in a patient. Further, again, representative examples of the tissue which can be reduced or eliminated by such drugs are provided by the instant disclosure; see, e.g., page 5, first paragraph. The invention is a directed to a process which lies in the manner of administration of the drug. As Judge Rich stated in *In re Durden Jr.*, 226 USPQ 359, 362 (Fed. Cir. 1985), "A process, after all, is a manipulation according to an algorithm, as we have learned in recent years - doing something to or with something according to a schema." A process invention has as its thrust the "manipulation" of a thing. The nature of that thing is of no import as long as it is amenable to the manipulation. The process may even be applicable to things that are yet to be discovered and still be the same process. As such, more precise definition of the reactants involved is not necessary to provide a complete and definite description of the invention herein under 35 U.S.C. §112. The situation is analogous here, the process is using known elements in a new way.

In view of what was known to one of ordinary skill in the art, e.g., as discussed in the Background of the instant specification, applicants' disclosure provides an adequate description under 35 U.S.C. §112, first paragraph. The PTO has provided no proof that the invention is in an unpredictable art area and the knowledge in the art of drugs for eliminating or reducing normal but undesired tissue belies such a position. Contrary to the statements in the Final Office Action, applicants' argument pertained to lack of proof of an unpredictable art area, not lack of proof of operability. Absent any proof of unpredictability or evidence of

reason to doubt the truth of applicants' disclosure, the PTO's burden of proof to support a 35 U.S.C. §112, first paragraph, rejection is not met.

As discussed in MPEP §2163, although there is a strong presumption of adequate description for an original claim, the issue of a lack of adequate written description may arise even for an original claim if the claim requires an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. Here all the elements of the claims are known in the art. The invention distinguishes from the known methods in that it involves localized administration of a controlled release drug formulation for the local elimination or reduction of normal, but undesired, tissue. But all the elements, i.e., the drug and what type of tissue a particular drug can eliminate or reduce, were known in the art. This is not disputed in the office action and, thus, under the PTO's own guidelines a 35 U.S.C. §112, first paragraph, rejection for lack of written description is not supported.

In the Final Office Action applicants' arguments based on claim 1 being an original claim were considered not persuasive on the grounds that the original claim issue only arises for a new matter rejection. This position is clearly in conflict with the PTO's own guidelines regarding written description in MPEP §2163.

Further, in the Final Office Action, it was alleged that applicants' reduction to practice example of TNF-α for fat tissue ablation was insufficient under the MPEP §2163 guidelines. Applicants urge that the guidelines do not require more than one example of a reduction to practice. This is because of the "strong presumption" involved when the claims are original claims. Further, even if applicants' reduction to practice were insufficient, this is not the only means of showing adequate description for an original claim. As discussed above, the

knowledge in the art of elements needed to carry out applicants' invention are sufficient when an original claim is involved, even if there were no reduction to practice.

Finally, regarding the overbreadth argument (which is not a sufficient basis for 35 U.S.C. §112 rejection) it is argued in the Final Office Action that applicants must describe the result and the means to accomplish the result. However, for all the reasons given above, it is urged that such description is provided. Applicants clearly described the broad terms of the result, i.e., "eliminating or reducing normal but undesired tissue in a patient," and the broad terms of the means for achieving the result, i.e., a "formulation comprising a substance which eliminates or prevents formation of the cells of the undesired tissue, said substance being provided in a controlled release carrier." Applicants then provide representative examples of both the result and the formulations for achieving it. Further, numerous examples of the drugs and of controlled release formulations for achieving such result were known in the art. Applicants need not describe that which is well known in the art to meet the 35 U.S.C. §112, first paragraph, requirements.

For the above reasons, applicants respectfully submit that the instant claims have adequate written description and the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

The Rejection under 35 U.S.C. §102

The rejection of claims 1-3, 5, 6, 9-12, 14 and 17 under 35 U.S.C. §102, as being anticipated by Goldenberg (WO 98/46211) is respectfully traversed.

Goldenberg discloses only methods wherein the patient is subject to a general effect by the drug. For example, in all the embodiments referring to Goldenberg's anti-obesity methods, the results are discussed in terms of overall weight of the patient (or animal model,

see, e.g, page 22) and not in terms of the loss of tissue in any particular local area, particularly not in the local area into which the drug is administered. Although Goldenberg does teach that its formulations may be administered by injection, it does not provide any disclosure that such injection results in elimination or reduction of the normal but undesired tissue in the local area of the injection. Although it is likely true that Goldenberg's systemic treatment for a general effect has the incidental result that the tissue (e.g., fat) is reduced in the area of the injection to the same extent as the rest of the body, such incidental result does not meet the terms of applicants' claims.

The only reasonable interpretation of the claim terms "by injection at a local area containing the undesired tissue such that the undesired tissue in the local area is eliminated or reduced" is that the elimination or reduction in tissue occurs in the local area of the injection exclusively or to a significantly higher degree than other areas of the body not subject to the injection. This would be the clear and only reasonable interpretation of the claim to one of ordinary skill in the art. To interpret that the "local area" limitations of the claim are met by methods for system-wide, general treatment of the patient by injection into the bloodstream would eviscerate any meaning of the "local area" terms. The understanding in the art of the meaning of local area as being contrasted from a general treatment was already previously discussed in overcoming the previous 35 U.S.C. §112, second paragraph, rejection. Additionally, as exemplified by the art cited by applicants in the specification, the term "local area" would be well understood in this art that a "local area" defines treatment of a discrete area of the body and is distinguished from treatments which affect the body as a whole. See, e.g., the definition of "local" in the attached excerpt from the "International Dictionary of Medicine and Biology" vol. II (1986).

The person of ordinary skill in the art is deemed to read the claim term not only in the

context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification; see, e.g., *Phillips v. AWH Corp. et al.*, _____ F.3d _____ (Appeal Nos. 03-1269, -1286) (Fed. Cir. 2005) (*en banc*); *Vitronics Corp. v. Conceptronic Inc.*, 90 F.3d 1576, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996). Here, the specification gives ample guidance as to the meaning of the "local area" terms in the claims, consistent with the art-recognized meaning. The specification distinguishes the inventive local administration from general administration in the Background section of the specification. Also in the Background, it points out other art which utilizes local administration methods for different effects. Thus, it is clear that local administration is a term used in the art having a defined meaning. Further, the specification gives representative examples of specific types of administration to achieve the local area treatment (see, e.g., page 6, third full paragraph, and paragraph bridging pages 6-7). Finally, the specification provides in vivo and in vitro examples with rat models demonstrating specific applications of the method and showing their localized effect (see pages 8-18 of the specification).

In view of this correct interpretation of the "local area" terms in the claims, it is again strongly urged that Goldenberg does not disclose a method wherein the sustained-release formulation is administered to the patient "by injection at a local area containing the undesired tissue such that the undesired tissue in the local area is eliminated or reduced." Goldenberg discloses only a general, systemic treatment and does not meet the correctly defined "local area" effect recited in the instant claims.

Accordingly, Goldenberg cannot anticipate the instant claims and the rejection under 35 U.S.C. §102 should be withdrawn.

The Rejections under 35 U.S.C. §103

The rejections of the claims under 35 U.S.C. §103, as being obvious over Goldenberg, alone, or in view of the Hutchinson, Ogawa or Johnson articles, Silvestri (U.S. Patent No. 5,126,147), or Silvestri, further in view of the Merwin article, are respectfully traversed.

The discussion of Goldenberg above in connection with the traversal of the 35 U.S.C. §102 rejection is incorporated herein by reference. To summarize, Goldenberg fails to disclose a method wherein the controlled release formulation is injected at a local area containing the normal but undesired tissue and the normal undesired tissue in the local area is eliminated or reduced. Applicants urge that Goldenberg also fails to suggest modifying its method to meet the local effect element of the instant claims.

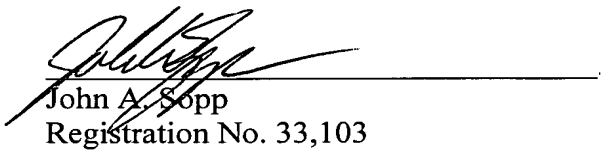
Goldenberg provides no teachings which give any hint to one of ordinary skill in the art that a controlled release formulation could be injected at a local area to eliminate or reduce normal but undesired tissue in that local area. To the contrary, all the teachings in Goldenberg relate to administration of a sustained-release formulation to achieve general effects on the patient, for example, overall weight loss. Similarly, all of the secondary references also relate only to systemic delivery of drugs to achieve a general effect. There is no suggestion in any of the references that a specific local area of the injection could be targeted. A general weight loss effect taught by the art suggests to one of ordinary skill in the art that the weight loss is relatively evenly distributed in the patient and, thus, is not suggestive of the elimination or reduction of tissue targeted to the local area of injection.

For the above reasons, it is urged that no combination of the cited art renders the claimed invention obvious to one of ordinary skill in the art. Thus, the rejections under 35 U.S.C. §103 should be withdrawn.

It is submitted that the application is in condition for allowance. But the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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Date: September 19, 2005